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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,493	06/22/2001	Gregor Cevc	500.1013	7718

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EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary

Application No.

09/887,493

Applicant(s)

CEVC, GREGOR

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7,9,11-14,21-24,26-41 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) 26-34,36-38 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7,9,11-14,21-24,35,39-41 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7, 9, 11-14, 21-24, 26-41, and 44-50 are currently pending.

Election/Restrictions

2. Applicant's election of Group I, claims 1-7, 9, 11-14, 21-24, 35-41, and 44-46, a cellulose derivative for species A, BHT for species B, methylparaben for species C, and clobetasol for species D in Paper No. 9, dated October 10, 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 26-34, 36-38, and 47-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
4. 1-7, 9, 11-14, 21-24, 35, 39-41, and 44-46 are examined on the merits.

Specification

The specification is objected to because it does not contain a brief description of the drawings.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

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Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. PCT/EP98/08421, filed December 23, 1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9, 11-14, 21-24, 35, 39-41, and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is indefinite because in line 5 it should state that the formulation "further comprises" a consistency builder, an antioxidant, or a microbicide. Currently the claim is confusing because without the use of "further comprising" it seems that the claimed formulation is only the consistency builder, the antioxidant, or the microbicide.

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6. Claim 5 is rendered indefinite by the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim. The parentheses in the claim that are associated with the chemical names of the polymers are acceptable. Unacceptable uses of parentheses are in lines 10 and 11.

7. Claim 7 is rendered indefinite by the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "hydrophilic polymers," and the claim also recites "including" specific types of polymers which is the narrower statement of the range/limitation. In addition, claims 7 and 9 improperly narrow the claim by using "including" in this manner. Claim 11 improperly narrows the claim by using "especially."

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9. Regarding claim 39, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 7, 11, 12, 14, 21-24, 35, 41, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by German Pat. No. 44 47 287 C1.

Applicant's claims are directed toward a topical composition that is able to penetrate the pores even when the pores are smaller than the diameter of the penetrants. This composition is disclosed by applicant as being described in DE '287 (see page 2, first paragraph of applicant's specification). DE '287 refers to the composition as "transferosomes." The transferosomes in DE '287 can contain the antioxidant BHT (see English translation, page 25, second paragraph). The transferosome can also contain glucocorticoids and mineral corticoids (see page 24 of English translation).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-7, 9, 11-14, 21-24, 35, 39-41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Pat. No. 44 47 287 C1 in view of US Pat. No. 5,322,685.

As stated above, DE '287 teaches the claimed formulation of transferosomes. However, DE '287 does not specifically teach adding cellulose derivatives, methylparaben, and the steroid clobetasol to the composition. US '685 teaches that these ingredients are known to be used in topical formulations. Clobetasol is taught to be used topically as an antiinflammatory (see column 2, lines 38-48). Cellulose derivatives are used to modify the viscosity of the composition and methylparaben is added as a preservative (see column 3, lines 55-59). Based on this teaching by US '685, a person of ordinary skill in the art would expect that the composition of DE '287 could be modified to include cellulose derivatives and methylparaben to improve the characteristics of the composition and to use the composition of DE '287 as a carrier for the topical steroid clobetasol. Therefore, an artisan of ordinary skill would have been motivated to modify the composition of DE '287 to include cellulose derivatives, methylparaben, and clobetasol.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some

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demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

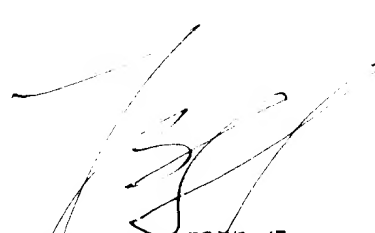
12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
November 20, 2002



LEON B. LANKFORD, JR
PRIMARY EXAMINER